K120504

Summary of Safety and Effectiveness
Liquichek Urine Toxicology Control

MAR 27 2012

1.0 **Submitter**

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Date of Summary Preparation

February 16th, 2012

2.0 **Device Identification**

Product Trade Name: Liquichek Urine Toxicology Control

- Liquichek Urine Toxicology Control Level S1O
- Liquichek Urine Toxicology Control Level S2O
- Liquichek Urine Toxicology Control Level S1O Low Opiate
- Liquichek Urine Toxicology Control Level S2O Low Opiate

Common Name:	Drug Mixture Control Materials
Classifications:	Class I
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Urine Toxicology Control (Screen Series)
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K033924

4.0 **Description of Device**

Liquichek Urine Toxicology Controls are prepared from human urine with added drugs of abuse and metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form for convenience.

5.0 **Intended Use**

Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the precision of laboratory urine toxicology screening procedures.

6.0 Comparison of the new device with the Predicate Device

Liquichek Urine Toxicology Control claims substantial equivalence to the Liquichek Urine Toxicology Control (Screen Series) currently in commercial distribution (K033924). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Liquichek Urine Toxicology Control *(New Device)*	Liquichek Urine Toxicology Control (Screen Series) *(Predicate Device, K033924)*
Similarities		
Intended Use	Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the precision of laboratory urine toxicology screening procedures.	Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology screening procedures.
Matrix	Human Urine	Human Urine
Form	Liquid	Liquid
Open Vial Stability	30 days at 2°C to 8 °C	30 days at 2°C to 8 °C
Differences		
Storage unopened (Shelf Life)	-20 to -70°C until expiration date	2 to 8°C until expiration date
Closed Vial (Thawed) Stability	45 days at 2°C to 8 °C	No Claim
Levels	Level S1O, S2O, S1O Low Opiate, S2O Low Opiate	Levels S1, S2, S3, S1 Low Opiate and S2 Low Opiate
Analytes	**Contains:** 11-Nor-Δ-9-THC-9-COOH Benzoylecgonine Ethanol Lysergic Acid Diethylamide (LSD) Methadone Methaqualone Morphine (Free) Oxazepam Phencyclidine (PCP) Propoxyphene Secobarbital d-Methamphetamine	**Contains:** 11-Nor-Δ-9-THC-9-COOH Benzoylecgonine Ethanol Lysergic Acid Diethylamide (LSD) Methadone Methaqualone Morphine (Free) Nordiazepam Nortriptyline Phencyclidine (PCP) Propoxyphene Secobarbital d-Amphetamine
	Does not contain: Nordiazepam Nortriptyline d-Amphetamine	**Does not contain:** d-Methamphetamine Oxazepam

7.0 Statement of Supporting Data

Stability studies have been performed for Liquichek Urine Toxicology control to determine the open vial, closed vial (thawed) and shelf life claims. Product claims are as follows:

7.1	**Open Vial:**	30 days at 2 to 8°C.
7.2	**Closed Vial (Thawed):**	45 days at 2 to 8°C.
7.3	**Shelf Life Stability**	2 Years at -20°C to -70°

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bio-Rad Laboratories, QSD
Ms. Elizabeth Platt
Regulatory Affairs Manager/Quality Assurance
9500 Jeronimo Road
Irvine, CA 92618-2017

MAR 27 2012

Re: K120504
Trade/Device Name: Liquichek Urine Toxicology Control
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I (Reserved)
Product Code: DIF
Dated: February 17, 2012
Received: February 21, 2012

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known):_____

Device Name: **Liquichek Urine Toxicology Control**

- Liquichek Urine Toxicology Control Level S1O
- Liquichek Urine Toxicology Control Level S2O
- Liquichek Urine Toxicology Control Level S1O Low Opiate
- Liquichek Urine Toxicology Control Level S2O Low Opiate

Indications for Use: **Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the precision of laboratory urine toxicology screening procedures.**

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(K) K120504